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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,452	12/11/2003	Jacob Bar-Tana	1567/70937-ZB/JPW/AG	2057

7590 05/03/2006

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EXAMINER

CARR, DEBORAH D

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,452	<b>Applicant(s)</b> BAR-TANA, JACOB	
	<b>Examiner</b> Deborah D. Carr	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/104,880.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/03, 9/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

***Election/Restrictions***

1. The Election Requirement dated 9 March 2006 has been withdrawn. Claims 29-34 will be examined during the prosecution of this application barring any amendments.

***Claim Rejections - 35 USC § 112***

2. Claims 30- rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of dyslipoproteinemia, does not reasonably provide enablement for inhibition of HNF-4 controlled gene transcription, increasing the levels of HDL cholesterol in a subjects plasma, lowering triglycerides in the plasma of a human subject accompanied by an increase in plasma levels of HDL cholesterol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It has been disclosed by applicants that the instant compound 3, 3, 14, 14-tetramethyl-hexadecane-1, 16-dioic acid can be used to treat dyslipoproteinemia, obesity, IGT/NIDDM, hypertension and coagulation/fibrinolysis defects there is no indication that the situations listed supra are encompassed by the known defects. Since there is no correlation presented, one would not expect the situations listed supra to be treatable by the instant compounds hence lack of enablement for these situations.

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3. Claims 29-34 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The therapeutically effective amount of 3, 3, 14, 14-tetramethyl-hexadecane-1, 16-dioic acid critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

There is no teaching in the specification as filed that would give direction as to what is considered to be the therapeutically effective amount of 3, 3, 14, 14-tetramethyl-hexadecane-1, 16-dioic acid needed to treat the defects or conditions recited in the claims listed supra. The specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention.

### ***Specification***

4. The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application-by-application number and filing date is required.

For objected alterations see page 10, line 12 under the section titled "Detailed Description of the Invention" and page 4, line 17.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 29 & 32 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Frenkel et al.

Frenkel et al. teaches that dyslipoproteinemia can be treating using  $\beta$ ,  $\beta'$ - tetramethyl-hexadecanedioic acid.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637.

The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access


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to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free).

  
DEBORAH D. CARR  
PRIMARY EXAMINER

ddc